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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,794	03/02/2006	Neil McGregor	Q89079	4232

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EXAMINER	
CRUZ, KATHRIEN ANN	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,794	MCGREGOR, NEIL	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *12-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/11/2005, 01/19/2007, 09/15/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-44 are pending.

Claims 12-44 have been withdrawn.

Claims 1-11 are examined herewith.

Claims 12-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 5, 2009.

Priority

This application is a national entry of PCT/AU04/00018 dated 01/09/2004. This application also claims foreign priority benefit of 2003900064 dated 01/09/2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of herpes viral infection (such as aphthous ulcers (cold sores), herpes simplex or zoster lesions or chicken pox lesions)

with the administration of citrate salt and/or succinate salt, does not reasonably provide enablement for the **prevention** or **prophylactically** treatment of herpes viral infection (such as aphthous ulcers (cold sores), herpes simplex or zoster lesions or chicken pox lesions).

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claims 1-11 are drawn to a method of treating or **prevention** herpes viral infection (such as aphthous ulcers (cold sores), herpes simplex or zoster lesions or chicken pox lesions) by administering a **prophylactically** effective amount of citrate salt and/or succinate salt.

Breadth of the claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass prevention of herpes symptoms in humans. Each defects may or may not be addressed by the administration of the claimed compounds. Applicants claim that not only can herpes be treated with thalidomide, but that it can also **prevent symptoms** with **prophylactically** effective amount of citrate salt and/or succinate salt.

Guidance of the Specification/Working Examples: Applicant has provided no guidance showing the actual "prevention" with prophylactic treatment of herpes. All the guidance are directed to the treatment of herpes rather than the prevention.

State of the Art: *While the state of the art is relatively high with regard to the* ***treatment of the*** symptoms of herpes, the state of the art with regard to **prevention** of all symptoms is underdeveloped. Therefore it is highly speculative that herpes is preventable as claimed.

Predictability/Unpredictability in the Art: There *is a general lack of predictability in the pharmaceutical art. In re Fisher, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970). It would be unpredictable for the skilled artisan to use the claimed formulation to prevent all forms of herpes because of the reasons stated above.*

The Quantitation of Experimentation Required: In order to practice Applicants invention, it would be necessary for one to conduct an exhaustive amount of experiments. Applicant would need to provide reasonable data showing that citrate salt and/or succinate salt can **prevent** herpes symptoms. Therefore, in order to practice the claimed invention, the amount of experimentation required would be considered undue and burdensome.

According, the method of **preventing** herpes symptoms with a **prophylactically** amount of citrate salt and/or succinate salt is not enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al., U.S. Patent 5,639,795.

Friedman teaches the administration of a combination of "release adjusting agents" that include amino acids, such as lysine, and sodium citrate in liquid polymer compositions to treat aphthous ulcers (cold sores), herpes simplex or zoster lesions and chicken pox lesions (e.g. blisters) (column 7, line 63, to column 8, line 3, as well as lines 51-57 and column 20, lines 28-40). The liquid polymer composition is preferably topically applied to mucous membranes and, in particular, to the oral mucosa. (column 11, lines 47-53). Lysine and sodium citrate are included in various formulations (Tables XIII-XVI, Example 19-E and Figures 9 and 10). Further, see claims 1 and 3, columns 38-40 where sodium citrate and lysine are clearly preferred components.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al., U.S. Patent 5,639,795 as applied to claim 1 above, and further in view of Sekut et al., 6,054,487.

Friedman as cited above.

Friedman fails to include a succinate salt in a formulation for the treatment of aphthous ulcers or herpes.

Sekut teaches the administration of pharmaceutically acceptable salts that include succinate salts, which may include cations based on the alkai and alkaline earth metals, such as sodium, lithium, potassium, calcium and magnesium in the treatment of aphthous ulcers (column 11, line 57, to column 12, line 21, as well as column 19, line 17, and claim 9, column 36).

It would have been obvious to one of ordinary skills in the art that in view of the combined teachings of Friedman and Sekut, one skilled in the dental or dermatological arts would have been motivated to prepare a composition comprising sodium citrate, lysine and a succinate salt for administration to patients suffering from recurrent aphthous ulcers (cold sores) and herpes infection. An amino acid, such as lysine, a

citrate salt, such as sodium citrate and various succinate salts are all established components in compositions for the treatment of aphthous ulcers (cold sores) and herpes as taught by both Friedman and Sekut.

For these reasons, the claimed subject matter is deemed to fail to be patentably distinguishable over the state of the art as represented by the cited reference. The claims are therefore, properly rejected under 35 U.S.C. 103.In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-11 are rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is

(571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1628

/San-ming Hui/
Primary Examiner, Art Unit 1628